

AMENDMENTS TO THE DRAWINGS:

Please add a new sheet of drawings, Figure 18.

REMARKS

In the Office Action dated December 7, 2009, the drawings were objected to. Claims 24-28 were rejected under 35 U.S.C. § 112, second paragraph. Claims 12, 13, 15-19, 21 and 23 were rejected under 35 U.S.C. § 1(a) as being unpatentable over Houston et al., U.S. Publication No. 2002/0179166, (Houston), in view of Evans et al., U.S. Patent No. 5,709,713, (Evans). Claim 20 was rejected as being unpatentable over Houston in view of Evans and in further view of Igaki et al., U.S. Patent No. 5,733,327 (Igaki). Claims 1, 3-6 and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Houston and Evans in further view of Hogan, U.S. Patent No. 6,569,191. Claims 9 and 10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Houston in view of Evans and in further view of Inderbitzen et al., U.S. Patent No. 5,484,411, (Inderbitzen). Claims 24-28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Houston in view of Evans and in further view of Nunez et al., U.S. Patent No. 6,569,023, (Nunez). For the reasons outlined in detail below, it is respectfully submitted that the pending claims are in condition for allowance over the art of record.

Independent Claim 12 and Dependent Claims 1-6, 9, 10, 13 and 15-23

Independent claim 12, along with several dependent claims, was rejected as being unpatentable over Houston in view of Evans. Applicant takes this opportunity to add the recitation of claim 1 to claim 12. Claim 1, in turn, was rejected as being unpatentable over Houston and Evans in further view of Hogan. In this connection, it was asserted that Houston in view of Evans discloses a stent 11 having a helix structure and formed of a synthetic material and having an outer wall that radially expands. It was admitted that the combination of Houston and Evans fails to disclose wall portions that have more of a resistance to extension than the helical portions. Hogan was said to teach an expandable stent wherein rigid longitudinal strips 40 are attached to the helically wound threads that form the wall of the stent and exert an increased longitudinally constricting force. Column 7, lines 1-12 and Figure 4 were identified in Hogan. It was then asserted that it would have been obvious to one of ordinary skill in

the art at the time the invention was made to have provided longitudinal extension resistance to the stent of the combination of Houston and Evans as taught by Hogan to increase radial expansion to obtain a desired final diameter. This rejection is respectfully traversed. In connection with Hogan, the reference states at column 7, lines 8-10 that the increased longitudinal constricting force "increases the radial expansion force." The modification proposed in the Office Action would result in the use of Hogan's strips 40 which extend only longitudinally. In contrast, amended claim 12 requires a helical portion which extends both longitudinally and circumferentially. Therefore, even if the three prior art references were combined as proposed by the Examiner, which combination applicants do not admit would have been obvious at the time the instant invention was made, it still would not meet the requirements of amended claim 12.

It is noted that Hogan does disclose in the embodiment of Figure 2, and at column 6, lines 33-38, a stent having a helical portion which extends longitudinally and circumferentially. More specifically, a helical thread 30 is identified in this regard. The embodiment of Figure 2 of Hogan was mentioned in the Office Action in connection with claim 3. However, claim 12 as amended requires that the helical portion, upon expansion of the stent from the collapsed condition to the expanded condition, resist extension more than the portions of the stent which are located adjacent to the helical portion. The helical thread 30 of Hogan seeks to do the opposite. Hogan states that the thread 30 "is more rigid than the other threads and thus exerts a greater radial expansion force." Therefore, the thread 30 in Hogan promotes radial expansion of the Hogan stent. In contrast, the helical portion of the stent recites in claim 12 locally resists extension and thus can cause the stent, when it is located in a fluid conduit, to have a flow lumen with a helical center line. This is discussed at length in the instant specification at page 8, lines 13-23, and in the section of the specification running from page 18, line 36 to page 19, line 2.

The effect of a stent helical portion which resists extension more than do adjacent stent portions is neither disclosed nor suggested by Hogan. Moreover, neither of these teachings is present in either of the other two applied references to Houston or Evans. As a result, the stent of claim 12 is not obvious over the proposed three-way

combination of Houston, Evans and Hogan. Moreover, claim 12 is also in condition for allowance over the remainder of the cited art in any combination.

Dependent claims 3-6, 13 and 15-23 merely further patentably define the detailed subject matter of their parent claim or each other. As such, these claims are also believed to be in condition for allowance over the applied three-way combination, as well as the remainder of the art of record.

Claims 9 and 10 were rejected as being unpatentable over Houston and Evans, in view of Inderbitzen. Inderbitzen was used for its teaching of an expandable balloon used in angioplasty procedures as including a longitudinally extending spiral wall 38 extending from the distal end to the proximal end of the balloon and formed integrally with the exterior surface of the balloon and radially restricting the expansion of the balloon along the longitudinally extending spiral path. Column 3, lines 45-53 and Figure 2 of Inderbitzen were noted. It was asserted that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have construed the balloon of the combination of Houston and Evans with a helical portion as taught by Inderbitzen to exhibit a low crossing profile and to avoid the need to rotate the balloon within the vessel to insure dilation.

However, even the proposed four way combination (adding Hogan) fails to teach or disclose the subject matter which is now recited by dependent claims 9 and 10. As such, these claims are also in condition for allowance over, not only the four way combination of Houston, Evans, Hogan and Inderbitzen, but also the remainder of the cited art.

Dependent claim 1 has been cancelled and its subject matter added to claim 12.

Independent Claim 24 and Dependent Claims 25-28

Claim 24 was said to be unpatentable over Houston in view of Evans and in further view of Nunez. Houston was said to disclose a conduit that may be a mesh stent 11 which appears to be expandable since it is disclosed as being collapsible. It is admitted that Houston does not expressly disclose its stent as being expandable. The Houston stent is said to have an expanded configuration that is substantially free of ribs

and having a helical center line and a helix angle of 8 degrees that is within the claimed range of less than or equal to 65 degrees. It is admitted that Houston fails to disclose an amplitude having a value of less than or equal to 0.7 of the internal diameter of the tubing and to expressly disclose a stent that is expandable from a collapsed configuration. It was then asserted that it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a tubing having a helical center line with the claimed value of an amplitude less than or equal to 0.7 of the internal diameter, since it has been held that discovering an optimal value of a result effective variable involves only routine skill in the art. Evans was said to teach a mesh stent having a radially compressible and expandable configuration. It was asserted that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the mesh stent of Houston with expansion and collapsing means as taught by Evans to release and remove the stent during and following the desired treatments.

It was further admitted that the combination of Houston and Evans fails to disclose a conduit having a helical center line that varies along the length of the stent. Nunez was said to teach a mesh stent (column 16, lines 22-36) having a helical center line (Figure 6) wherein the center line varies or changes from one axis to another, the helical center line having the capability of introducing a gentle swirl to increase the swirling of the fluid. It was then asserted that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the mesh stent of the combination of Houston and Evans with a varying helical center line as taught by Nunez to avoid the need to customize stents by using sutures. This rejection is respectfully traversed.

The Office Action considers that Nunez discloses the feature of a helical center line that varies to introduce a general swirl at the upstream and to increase swirl in a downstream direction. However, Nunez does not even relate to helical stents, much less to a stent having these features. The embodiments of Figures 6 and 7 are "sinusoidal shaped grafts" (see column 9, lines 1 and 29) with an "S configuration" (see column 9, lines 9-10 and 48). Contrary to the contention made in the Office Action, Figures 6 and 7 of Nunez simply do not show helical center lines with varying angle,

amplitude or pitch. All that varies in Figure 7 is the diameter of the graft. Moreover, there is no mention of the desire to provide swirl flow in Nunez, let alone a swirl flow that increases in a downstream direction as called for in independent claim 24.

As a result, even the proposed three-way combination of Houston, Evans and Nunez do not disclose a stent having a varying helical center line to introduce a gentle swirl, as is recited in independent claim 24. Therefore, claim 24 patentably defines over the applied three-way combination, as well as the remainder of the cited art.

Applicant takes this opportunity to cancel claims 25-27 without prejudice.

Dependent claim 28, which merely further patentably defines the detailed subject matter of its parent claim or each other, is also believed to be in condition for allowance over the proposed three-way combination, as well as the remainder of the art of record.

New Claim 29

Applicant takes this opportunity to submit a new claim 29. This claim recites a method of inserting a stent in a fluid conduit of a human or animal body. The method comprises inserting the stent when in a collapsed condition, and expanding the stent to an expanded condition. The stent, in the expanded condition, causes the fluid conduit in the area of the stent to have a flow lumen with a center line which follows a substantially helical path. The stent when expanded ex vivo has a helix angle of less than or equal to 65 degrees and a helical center line having an amplitude less than or equal to 0.7 of the internal diameter of the stent. A smooth inner periphery is provided for the stent in the expanded condition such that it is substantially free of ribs which would project into the flow lumen of the conduit.

It is respectfully submitted that new claim 29 is clearly patentable over the Houston reference which explicitly pertains to an external stent. Moreover, this claim patentably defines over Houston in combination with any of the other applied or cited art. As noted in response to the previous Office Action, there are many reasons why the person of ordinary skill in the art could not and would not insert an external stent, such as Houston, within a vessel.

Drawings

It was asserted in the Office Action that the drawings were objected to because the recitation of the "stent having a helical center line that varies" is not shown in the drawings. Applicants respectfully submit that the varying helical center line of the stent is shown in the embodiments illustrated in Figures 14-17. However, it is simply not visible in these figures. Therefore, applicants submit herewith a new drawing, Figure 18 to better illustrate this feature.

Support for the recitation of the stent having a helical center line that varies is provided on page 6 of the application in the paragraph spanning lines 28-37. There, it is stated that variation of the amplitude can be achieved by increasing or decreasing the resistance to extension provided by the helical portion while variation in pitch can be achieved by varying the pitch of the helical portion itself.

As a result, it is respectfully submitted that no new subject matter has been added.

Once approval has been indicated for newly submitted Figure 18, applicant will proceed to amend the specification as necessary in order to reference Figure 18.

In view of the foregoing, it is respectfully submitted that the pending claims are in condition for allowance over the art of record. Such allowance is earnestly solicited.

Respectfully submitted,

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Date

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